



Surasana Latex Co., Ltd.

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To: Food and Drug Administration
5630 Fishers Lane
Rm. No. 1061
Docket Management Br. HFA 305
Rockville MD 20852
From: Phira T. Suwan (Mr.)
Date: November 26, 1999

Comments on Proposed Medical Gloves Regulation by :
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1. **PROTEIN COUNT:** The proposed dissolvable protein count of 1,200 ug per glove regardless of size is very unscientific and unfair. The fact is the largest (size 9 ½) when compared to size 5 ½ or 6 has almost double the weight and surface area. It is therefore illogical to set the same figure to cover every size. A ug/g is more practical and fair.
2. **PROTEIN EXTRACTION METHOD:**
Since the intended purpose is to protect the wearer of the glove, protein count should only be made on the donning side only.
3. **TENSILE STRENGTH:** It is grossly unfair to set a much higher standard on Natural Latex glove comparing to Nitrile. Both types of glove are used under the same conditions for the same purposes. This high tensile strength requirement greatly hinders efforts to reduce protein content of latex gloves. Thickness of the tested piece should also not be part of the equation As long as overall strength meets the set standard its purpose is fully served.
For example: Chlorination is a very effective way to de-proteinize latex glove but has an adverse effect on its tensile strength especially after aging.
(24 vs 17 before aging 18 vs 12 after aging in Mpa. Higher figures are ASTM standard for Latex Surgical Glove. Lower ones are for Nitrile.)

Phira T. Suwan
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